AUG 1 2000

510(K) SUMMARY

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Date: May 3, 2000

Submitter:

IOMED, Inc.
3385 West 1820 South
Salt Lake City UT 84104
Tel: (801) 975-1191
Fax: (801) 972-9072

Contact:

W. Tim Miller
Executive Vice President
General Manager, Clinical Systems

Device Name:

Iontophoresis Device
Iontophoretic Device Modification
Phoresor® Model PM2000

Predicate Device:

Iontophoresis Device
Phoresor® Model PM900
K974855 & K982668

Description of Device:

An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes. Iontophoresis technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered into and across the skin by iontophoresis is dependent upon the charge and size (molecular weight) of the ion, the strength of the electrical current being applied, electrode composition, duration of current flow, and numerous other factors.

The Phoresor® Model PM2000 iontophoretic device is a battery-powered, solid state, microprocessor-controlled device which controls current strength and duration, calculates total charge delivered, and monitors current flow and electrode/tissue impedance.

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Intended Use of Device:

Indications for use of the predicate and Phoresor® Model PM2000 iontophoretic drug delivery device are identical. The Phoresor Iontophoretic Drug Delivery System is indicated for the production of local dermal anesthesia using Iontocaine™ (brand of lidocaine hydrochloride 2% and epinephrine 1:100,000 Topical Solution).

Technical Characteristics:

The Phoresor® Model PM2000 iontophoretic device and the presently marketed Phoresor® Model PM900 have the same technical characteristics except that the marketed Phoresor®, PM2000 device is smaller in size, lighter in weight, powered by button cell batteries instead of a 9 volt battery, uses a common connector instead of lead wires to connect to the electrodes, uses less output power than the Phoresor® Model PM900 (240 mWatts versus 280 mWatts) and uses less output voltage than the Phoresor® Model PM900.

Non-clinical Performance Summary:

Testing data confirms that the output(s) of the Phoresor® Model PM2000 are functionally identical to the predicate device, the IOMED Phoresor® Model PM900.

Conclusions:

Through non-clinical testing, design review, analysis and validation, and failure mode and effects analysis, the IOMED Phoresor® Model PM2000 is found to be substantially equivalent to the IOMED Phoresor® Model PM900.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

Mr. W. Tim Miller
Executive Vice President
Iomed, Inc.
3385 West 1820 South
Salt Lake City, Utah 84104

Re: K001410
Trade Name: Phoresor® Model PM 2000
Regulatory Class: II
Product Code: KTB
Dated: May 3, 2000
Received: May 4, 2000

Dear Mr. Miller

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. This substantially equivalent decision applies only to the use of your device for iontophoretic dermal delivery of Iontocaine™. You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Our substantially equivalent decision does not apply to drugs other than Iontocaine that you might label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M. D.
Division of General and Restorative Device
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850
Tel (301) 594-1296

This letter immediately will allow you to begin marketing your devices as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for question on the promotion and advertising, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its

Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M. D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF

INDICATIONS FOR USE

Indications for use of both the predicate device and submitted device are identical.

The Phoresor Iontophoretic Drug Delivery System is indicated for the production of local dermal anesthesia using Iontocaine™ (brand of lidocaine hydrochloride 2% and epinephrine 1:100,000 Topical Solution).

Donna R. Bochman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001410